2. STUDY SYNOPSIS

Name of Sponsor: Facet Biotech Corporation **Company Conducting Study:** Biogen Idec Inc.	**Individual Study Table Referring to Part <> of the Dossier** **Volume:** **Page:**	***(For National Authority Use only)***
Name of Finished Product: Volociximab (M200)	**Name of Active Ingredient:** Volociximab (M200)	**Study Indication:** Advanced Epithelial Ovarian Cancer or Primary Peritoneal Cancer

Title of Study:

A Phase 2, Single-Arm Study of Volociximab Monotherapy in Subjects with Platinum-Resistant Advanced Epithelial Ovarian Cancer or Primary Peritoneal Cancer

Principal Investigator:

[redacted] United States (US)

Study Period: Date of first treatment: 18 September 2007 Date of early study termination: 22 April 2008	**Phase of Development:** 2

Study Objectives:

Primary objective:

- To evaluate the efficacy of volociximab when administered at 15 mg/kg once a week (qwk) in subjects with platinum-resistant, advanced epithelial ovarian cancer or primary peritoneal cancer.

Secondary objectives:

- To evaluate the safety and tolerability of volociximab when administered at 15 mg/kg qwk.
- To evaluate the pharmacokinetic (PK) parameters of volociximab when administered at 15 mg/kg qwk.

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Study Objectives (continued):

Additional objectives:

- To evaluate the pharmacodynamic activity and mechanism of action of volociximab using multiple biologic assessments, including studies of serum and whole blood protein and cellular biomarkers.
- To investigate the potential relationship between tumor expressions of $\alpha5\beta1$ or other relevant markers and clinical response to volociximab.
- To measure the concentration of volociximab and protein markers in ascitic fluid obtained from subjects in whom paracentesis can be safely performed and to evaluate potential correlations with clinical outcomes.

Study Design:

The protocol was amended twice. A country-specific protocol amendment for the United Kingdom (UK) was issued on 27 August 2007 (Version 1a1), and a global protocol amendment was issued on 14 February 2008 (Version 2). All subjects were enrolled under Version 1 of the protocol. The following methodology sections are based on Version 2 of the protocol.

This was a Phase 2, multicenter, open-label, 2-stage study. In Stage 1, 23 subjects were to be treated with volociximab 15 mg/kg qwk until disease progression or unacceptable toxicity occurred. If ≥3/23 evaluable subjects in Stage 1 achieved a complete response (CR) or partial response (PR) per the Response Evaluation Criteria in Solid Tumors (RECIST, Version 1.0), up to 33 additional evaluable subjects were to be enrolled and treated in Stage 2 with volociximab 15 mg/kg qwk. An evaluable subject was defined as any subject who had at least 1 on-study response assessment and met either of the following conditions: had received at least 4 infusions of volociximab or discontinued study treatment after fewer than 4 infusions for safety reasons, death, or lack of efficacy.

Subjects who achieved stable disease (SD) or better per RECIST were eligible to continue receiving volociximab at the same dose and schedule until disease progression or unacceptable toxicity occurred.

Number of Subjects (Planned and Analyzed):

Planned: 56 evaluable subjects were to be enrolled at approximately 30 study sites in North America and the UK - 23 subjects in Stage 1 and up to 33 subjects in Stage 2.

Analyzed: Sixteen subjects were enrolled at 11 study sites in North America and received at least part of an infusion of study treatment in Stage 1. No subjects were enrolled in Stage 2 since the study was terminated early.

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Study Population:

Inclusion criteria:

1. Must give written informed consent and any authorizations required by local law (e.g., Protected Health Information).
2. Females aged ≥18 years old at the time of informed consent.
3. Advanced (Stage III or IV), histologically documented epithelial ovarian cancer or primary peritoneal cancer (excluding small, round-cell histologies).
4. Radiologically documented evidence of progressive disease.
5. Platinum-resistant disease defined as having a best response of SD or disease progression during or within 6 months of discontinuing a platinum-based chemotherapy (carboplatinum, cisplatinum, or another organoplatinum compound).
6. Progression during or following treatment with topotecan or liposomal doxorubicin.
7. At least 2, but not more than 3 prior chemotherapy regimens including a taxane/platinum-based therapy. If taxane and platinum were not given as a combined regimen, the subject must have received each drug as part of a different regimen. (Hormonal therapies [e.g., tamoxifen, selective estrogen receptor modulators, aromatase inhibitors] are not considered to be prior chemotherapy.)
8. At least 1 measurable target lesion in accordance with RECIST criteria to assess clinical response (tumors within a previously irradiated field are designated as non-target).
9. ECOG Performance Status ≤1.
10. Life expectancy >12 weeks.
11. Available paraffin block or unstained paraffin sections on glass slides containing representative tumor tissue from a previous tumor biopsy/resection. (Tumor tissue from the most recent biopsy is preferred.)

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Inclusion criteria (continued):

12. Subjects of childbearing potential must be willing to practice effective contraception during the study and be willing and able to continue contraception for at least 6 months after their last dose of study treatment (about 5 half lives). Effective contraception methods are only required for subjects who are of childbearing potential upon enrollment into the study. Acceptable methods of contraception include any of the following: oral, depot, or injectable hormonal contraceptives; intrauterine devices or intrauterine system; NuvaRing®; birth control patch, or double-barrier contraception. Double-barrier contraception must consist of 2 of the following: condom and occlusive cap (e.g., female condom, diaphragm or cervical/vault caps) with spermicidal (foam, gel, film, cream, or suppository), cap, shield, sponge, spermicide. The only exceptions to contraception are: subject is postmenopausal for at least 1 year before Study Day 1, subject abstains from sexual intercourse, or subject or partner is surgically sterile (i.e., vasectomy, no uterus or no ovaries. Note: subjects who have their fallopian tubes ligated are not considered surgically sterile.)

Exclusion criteria:

1. Screening clinical laboratory values:
   - Absolute neutrophil count <1500/μL
   - Platelet count <75,000/μL
   - Hemoglobin <8.5 g/dL (hemoglobin may be supported by transfusion, erythropoietin, or other approved hematopoietic growth factors; darbopoeitin [Aranesp®] is permitted)
   - Serum bilirubin >2.0 × upper limit of normal (ULN)
   - Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) >2.5 × ULN (AST and ALT >5 × ULN for subjects with liver metastasis)
   - Serum creatinine >2.0 mg/dL
   - International normalized ratio >1.5
   - Activated partial thromboplastin time >1.5 × ULN
2. Clinically significant peripheral vascular disease.
3. Non-epithelial ovarian tumors.
4. Active infection requiring systemic antibiotics, antivirals, or antifungals, including human immunodeficiency virus/acquired immunodeficiency syndrome, hepatitis B, or hepatitis C infection.

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Exclusion criteria (continued):

5. History of abdominal fistula, gastrointestinal (GI) perforation, or intra-abdominal abscess within 6 months prior to Day 1.
6. Serious, non-healing wound, or bone fracture.
7. Known central nervous system or brain metastases.
8. History of uncontrolled psychiatric condition within 6 months prior to Day 1.
9. History of other malignancies within 3 years of Day 1, except for adequately treated carcinoma in situ of the cervix, ductal carcinoma in situ of breast, basal/squamous cell skin cancer, or Stage 1 or 2 endometrial cancer.
10. Evidence of autoimmune disease, including, but not limited to, ulcerative colitis, Crohn's disease, rheumatoid arthritis, systemic lupus erythematosus scleroderma, or another disease in which immune function or immune competence is known to be impaired.
11. Any history of lymphoproliferative disorder.
12. Known human anti-murine antibody and/or human anti-chimeric antibody.
13. Any medical condition that may be exacerbated by bleeding, including a known bleeding disorder such as a coagulation defect, thrombocytopenia, active gastric or duodenal ulcer, or history of GI bleeding.
14. Significant hemoptysis within one year prior to Study Day 1.
15. Any investigational anti-cancer therapy within 4 weeks prior to Day 1 if half-life is unknown or within 5 half-lives if half-life is known.
16. Any non-investigational, anti-cancer therapy within 4 weeks prior to Day 1 if half-life is unknown or within 5 half-lives if half-life is known. (After discussion with the Medical Director, the washout period may be shortened if the subject has recovered from any related acute toxicity and there is an urgent need for treatment.)
17. Prior treatment with anti-angiogenic agents.
18. Subjects who require treatment with an anti-coagulant with the exception of low-dose aspirin (≤81 mg/day), Plavix® (≤75 mg/day), warfarin (≤1 mg/day), or heparin for IV catheter patency. Aspirin and Plavix in combination are not allowed. Non-steroidal anti-inflammatory drugs are allowed.
19. Subjects who are taking concomitant immunomodulatory agents, including, but not limited to, interferons, interleukins, systemic steroids, cyclosporine, tacrolimus, calcineurin inhibitors, chronic low-dose methotrexate, or azathioprine. (The use of inhaled or intranasal steroids or oral prednisone at a dose of ≤10 mg/day steroid or its equivalent are permitted.)

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Exclusion criteria (continued):

20. Active, unstable severe cardiovascular disease, including poorly controlled angina, congestive heart failure, arrhythmias, myocardial infarction, cardiomyopathy, atrioventricular block, electrocardiogram (ECG) evidence of acute ischemia, or significant conduction abnormality.
21. History of thromboembolic or cerebrovascular events, such as stroke, or transient ischemic attack. (Note: Prior history of deep vein thrombosis will not exclude subjects from participating in this study.)
22. Pregnant (positive pregnancy test) or lactating.
23. Inability to comply with study and follow-up procedures.
24. Any condition that, in the opinion of the Investigator, makes the subject unsuitable for study participation.
25. Known hypersensitivity to murine or chimeric antibodies.
26. Major surgery within 4 weeks prior to Day 1.

Study Treatment, Dose, Mode of Administration, Batch Number(s):

Volociximab (15 mg/kg) was administered by IV infusion.

Two lots of volociximab were used during the study: Lots [redacted]

Duration of Treatment and Follow-Up:

Treatment Period:

Subjects were to report to the study site to receive IV infusions of 15 mg/kg of volociximab qwk for 8 weeks. Disease response was to be assessed every 8 weeks during the treatment period, and subjects with SD or better at each disease assessment visit were eligible to continue receiving volociximab until disease progression or unacceptable toxicity.

When subjects discontinued volociximab, they were to return to the study site approximately 4 weeks after the last infusion of volociximab to complete End of Treatment Visit procedures and evaluations.

60-Day Post-Treatment Follow-Up Visit:

Approximately 60 days after the last infusion of volociximab, the study site staff were to provide Biogen Idec with information on continuation of response (if applicable), disease progression, first subsequent cancer therapy, survival, adverse events (AEs) (with particular emphasis on events considered possibly related or related to study treatment and neurological signs or symptoms), and serious adverse events (SAEs) (regardless of relationship to study treatment).

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Duration of Treatment and Follow-Up (continued):

Long-Term Follow-Up:

After the 60-day Post-Treatment Follow-Up Visit, subjects were to be followed at 3-month intervals for the first year and every 6 months thereafter for information on continuation of response (if applicable), disease progression, first subsequent cancer therapy, survival, AEs/SAEs (particularly those considered possibly related or related to study treatment and neurological signs or symptoms). Long-term follow-up was to continue until the subject died, was lost to follow-up, or withdrew informed consent.

On 22 April 2008, Biogen Idec and Facet decided to terminate the study early as it was unlikely the efficacy criteria required to advance to Stage 2 of the study would be met. On 22 September 2008, a decision was also made to withdraw all subjects who were in long-term follow-up from the study and to close out all remaining open sites. All subjects who remained in long-term follow-up had begun subsequent anti-cancer therapies, which confounded survival data and supported the decision to terminate data collection.

Criteria for Evaluation:

Efficacy: The primary efficacy endpoint was objective response rate, defined as the proportion of subjects who had a CR or PR. Secondary efficacy endpoints included progression-free survival (PFS), 6-month PFS rate, duration of response, overall survival, and CA-125. Disease response was evaluated using RECIST.

Safety: Safety evaluations included physical examinations; vital sign and weight measurements; AE and SAE recording; hematology and blood chemistry analyses; urinalysis; electrocardiogram evaluations; and measurement of anti-volociximab antibody formation. The severity of each AE was assessed by the Investigator using the adult National Cancer Institute Common Terminology Criteria for Adverse Events (Version 3.0). In this study, the relationship of each AE to study treatment was classified by the Investigator as unrelated, unlikely related, possibly related, or related to study treatment. "Related AEs" were considered to be possibly related or related to study treatment. "Unrelated AEs" were considered to be unrelated or unlikely related to study treatment.

Pharmacokinetics: PK endpoints included serum concentrations of volociximab, clearance, volume of distribution, and elimination half-life.

Pharmacodynamics: Exploratory pharmacodynamic endpoints included the following:

- Analysis of serum protein biomarkers by Luminex multiplex assay and possibly proteomic approaches.
- Analysis of circulating tumor cells, circulating endothelial cells, and circulating endothelial progenitor cells.
- Analysis of archived paraffin-embedded tumor samples by immunohistochemistry and possibly proteomic approaches.
- Quantitation of volociximab concentration and possible analysis of other protein biomarkers in ascitic fluid by enzyme-linked immunosorbent assay or proteomic approaches.

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Statistical Methods:

Demographics and baseline characteristics: All demographic and baseline disease characteristic analyses were performed on the Full Analysis Population, defined as all subjects who received any part of an infusion of volociximab. Continuous variables were summarized using descriptive statistics (N, mean, standard deviation, median, minimum, and maximum), while categorical variables were summarized using frequencies and percentages (n, %).

Subject Disposition: Subject disposition analysis was performed on the Full Analysis Population. The number and percentage of subjects dosed and who discontinued study treatment were summarized. The number of subjects enrolled by study site was summarized.

Efficacy: The primary efficacy endpoint (ORR) was performed on the Evaluable Population, defined as all subjects who had at least 1 on-study response assessment and met either of the following conditions: had received at least 4 infusions of volociximab or discontinued study treatment after fewer than 4 infusions for safety reasons, death, or lack of efficacy. All other efficacy analyses were to be based on the Full Analysis Population. The study was terminated early due to insufficient evidence of efficacy; therefore, limited efficacy analyses are included in this abbreviated report. Objective response was summarized for response assessment visits using descriptive statistics (n, %). Target and non-target lesion measurements were listed by subject.

Pharmacokinetics: PK analyses were to be performed on data from the PK Population, defined as all enrolled subjects who received any part of an infusion of study treatment and have at least 1 sample collected for PK analysis. The study was terminated early due to insufficient evidence of efficacy; therefore, limited PK analyses are included in this abbreviated report. Volociximab serum concentrations were listed by subject, and the group results were summarized by visit using descriptive statistics (N, mean, standard deviation, median).

Safety: Safety analyses were performed on the Safety Population, defined as all subjects who received any part of an infusion of volociximab. The incidence of AEs was summarized by system organ class, preferred term, and toxicity grade. Overall AEs, related AEs, SAEs, and deaths were listed by subject. Subject listings for clinical laboratory parameters, vital signs measurements, physical examination findings, urinalysis results, anti-volociximab antibody formation were provided. Shift tables for clinical laboratory parameters were created.

Pharmacodynamics: Due to the insufficient evidence of efficacy observed in this study, exploratory analyses results are not included in this report.

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Results:

Subject disposition:

- Sixteen subjects were enrolled at 11 study sites in North America.
- All subjects received at least part of an infusion of 15 mg/kg volociximab.
- No subject remained on study at the time of database lock.
- Reasons for discontinuing study treatment included: disease progression (12 subjects), an AE (1 subject), death (1 subject), consent withdrawn (1 subject), and Investigator decision (1 subject).

Demographics and baseline disease characteristics:

- All 16 subjects were White females.
- The median age of 61 years (54 to 80 years).
- Twelve subjects (75%) had epithelial ovarian cancer; 4 subjects (25%) had primary peritoneal cancer.
- Nine subjects (56%) had Stage III disease; 7 (44%) had Stage IV disease.
- All subjects were platinum-resistant and had progressive disease after at least 1 prior cancer therapy. The median number of prior cancer regimens was 3 (2 to 4).

Efficacy:

- A review of the efficacy data from the first 13 evaluable subjects showed that 0 of 13 subjects had a response. Under the alternative hypothesis that the true response rate is 30%, the probability of observing 0 responses out of the first 13 evaluable subjects is 0.01. In addition, under the null hypothesis that the true response rate is 15%, the probability of observing 3 responders out of the next 10 evaluable subjects (to justify proceeding to Stage 2 of this study) is 0.18.
- Biogen Idec and Facet decided to terminate the study early as it was unlikely the efficacy criteria required to advance to Stage 2 of the study would be met and that the study would ultimately result in rejection of the null hypothesis.

Safety:

- AEs were reported in all 16 subjects (100%) who received study treatment.
- The most common (≥20%) AEs regardless of causality were fatigue, nausea, abdominal distension, headache, pyrexia, abdominal pain, anorexia, constipation, insomnia, and vomiting.
- Half of all subjects treated (50%) experienced AEs ≥Grade 3 regardless of causality as their most severe AE. Seven subjects (44%) experienced Grade 3 AEs. Two subjects (12%) experienced Grade 4 AEs: fatigue and reversible posterior leukoencephalopathy syndrome. Three subjects (19%) experienced Grade 5 (fatal) AEs: respiratory failure (2 subjects each) and disease progression (1 subject).

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Results (continued):

Safety (continued):

- Twelve (75%) subjects experienced at least 1 related AE; the most common (≥20%) were headache and fatigue. The majority of subjects (75%) who experienced related AEs had AEs ≤Grade 2 as their most severe AE.
- Fourteen SAEs were experienced by 8 subjects. Four subjects experienced related SAEs: Grade 3 hyponatremia (Subject [redacted]), Grade 4 reversible posterior leukoencephalopathy syndrome (Subject [redacted]), Grade 3 pulmonary embolism (Subject [redacted] , and Grade 5 (fatal) respiratory failure (Subject [redacted]). All other SAEs were considered by Investigators to be unrelated to study treatment.
- Evaluation of AEs typically associated with other anti-angiogenic drugs (thromboembolic and hemorrhagic events, hypertension, and proteinuria), AEs associated with other anti-antegrins (progressive multifocal leukoencephalopathy), as well as late-emerging AEs (AEs occurring during or within 24 hours after a volociximab infusion) revealed no safety issues of clinical concern with 15 mg/kg volociximab infused qwk in this study.
- One subject discontinued study treatment due to an AE (Grade 3 deep vein thrombosis unlikely related to study treatment).
- Four subjects experienced a total of 11 late-emerging AEs (defined as AEs that occurred at least 30 days following each subject's last infusion). Nine of the 11 events were ≤Grade 2 and were unrelated to volociximab. Two subjects experienced late-emerging AEs ≥Grade 3; both were considered related to volociximab and reported as SAEs: Grade 3 pulmonary embolism approximately 2 months after the subject's last infusion and Grade 4 reversible posterior leukoencephalopathy syndrome 39 days after the subject's last infusion.
- Five subjects died: 3 due to progressive disease, 1 due to respiratory failure, and 1 from multiple causes (respiratory failure, lymphangitis carcinomatosis, and disease progression). Only 1 of the 5 deaths occurred on study (from multiple causes). All other deaths occurred during the long-term follow-up portion of the study. One death that occurred in long-term follow-up was considered possibly related to study treatment (respiratory failure). All other deaths were considered unrelated to study treatment.
- Evaluation of vital sign measurements, physical examination findings, ECG results, hematology, blood chemistry, and urinalysis revealed no safety issues of clinical concern.
- Anti-volociximab antibody data were available on 12 subjects (75%) at both baseline and at least 1 post-treatment timepoint. None of these subjects developed detectable antibody titers post-treatment in this study.

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Results (continued):

Pharmacokinetics:

- Volociximab serum concentrations accumulated after the first infusion with trough concentrations continuing to increase through the fourth dose of Treatment Cycle 1. Only 1 subject had post-treatment serum concentrations measured in Treatment Cycle 2.
- The mean maximum observed concentration was 1202.88 µg/mL (60 minutes post-infusion on Day 50), and the trough concentration observed after the initial dose of volociximab was 279.31 µg/mL (preinfusion on Day 15).
- There was insufficient clinical activity in Stage 1 of the study to warrant performing a population-based PK analysis to estimate individual and group mean PK parameters.

Pharmacodynamics:

- Due to the insufficient efficacy observed in this study, exploratory analyses results are not included in this report.

Conclusions:

- Volociximab appeared to be tolerated when administered by IV infusion qwk at a dose of 15 mg/kg in subjects with platinum-resistant, advanced epithelial ovarian cancer or primary peritoneal cancer.
- Biogen Idec and Facet decided to terminate the study early as it was unlikely the efficacy criteria required to advance to Stage 2 of the study would be met.
- The insufficient efficacy did not appear to be related to subthreshold serum concentrations of volociximab. Mean trough serum concentrations of volociximab were above 150 µg/mL throughout the treatment period. This concentration correlated with efficacy in preclinical xenograft tumor growth inhibition studies.

Publications Based on the Study:

Matthews CM, Ho SN, Barve M et al. A phase 2, single-arm study of volociximab (an anti-a5 beta 1 integrin antibody) monotherapy in patients with platinum-resistant advanced epithelial ovarian cancer or primary peritoneal cancer. European Journal of Cancer, Supplement 2008; 6 (12):164-5.

Date of Report: 06 April 2009